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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,533	06/26/2003	James M. Rhodes	DEP5054	5756
27777	7590	08/10/2006	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			ROGERS, KRISTIN D	
		ART UNIT	PAPER NUMBER	
			3736	

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/606,533	RHODES ET AL.
	Examiner Kristin D. Rogers	Art Unit 3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 19 May 2006.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-7, 9, 11-19 and 21-24 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-7, 9, 11-19 and 21-24 is/are rejected.
- 7) Claim(s) 23 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

<ol style="list-style-type: none"> <li>1)<input type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2)<input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3)<input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.</li> </ol>	<ol style="list-style-type: none"> <li>4)<input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.</li> <li>5)<input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</li> <li>6)<input type="checkbox"/> Other: _____.</li> </ol>
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## **DETAILED ACTION**

### ***Claim Objections***

1. Regarding the claim objection of Claim 23, Applicant's amending claim 23 to recite the radius of curvature in centimeters does not overcome the objection. Applicant is advised to see the definition of radius of curvature.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In light of the Applicant's disclosure, it is unclear as to how the claimed invention can function without a mechanical connection between the lever and the slide member.

### ***Claim Rejections - 35 USC § 102***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 16-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Shutt et al. (5507772). In regard to claim 16, Shutt et al. shows a disposable surgical tool module 140 for use with a separate actuator module 12. The tool module 140 has

proximal 144 and distal 146 ends, hollow elongate support member at the distal end of housing 142 with free distal end 146 having an opening, a surgical implement capable of motion in the proximal-distal direction 152, a slide member 154 with a slot 156, the housing 142 having an opening aligned with the slot 156 of slide member 154, and the tool module 140 is free from any structure for moving the slide member in the proximal direction (Figure 11). In regard to claim 17, the surgical tool module 140 comprises a kit with an actuator module 140 including a handle 20 and a lever 24 pivotably connected to handle 20 via coupler 26 (Figure 1). In regard to claim 18, Shutt shows an elongate rod 18 and a tissue manipulator 16 in which the elongate rod 18 is received in support member 14. In regard to claim 19, Shutt shows the surgical tool module 140 comprising a spring 204 in the housing (column 14, lines 5, 16-25).

***Claim Rejections - 35 USC § 103***

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lucey et al. (5782834) in view of Shutt et al. In regard to claim 1, Lucey et al. shows a surgical instrument 10 with a proximal and distal end, a handle 25 curved for gripping, a hollow elongate support member 14, a slide member 34, a through-slot 94 between the two ends, a lever 24 including a handpiece trigger for gripping, a pivotal connection 136 including an integral drive portion on the other side of the pivotal connection 136 and an integral cam portion (shown in Figure 2, not numbered), and a spring 146. Lucey et al. lacks an integral cam received in the through-slot in the slide member, a drive surface,

and a through-slot at the drive surface. Shutt et al. teaches a disposable surgical tool module 140, a slide member 154 having a front end near 140 and back end near 192, with through-slot 156 of slide member 154, and through-slot 218 at drive surface 142 located on the proximal side of support member 20 for the purpose of receiving integral cam 210 (Figure 16). In regard to claim 2, Lucey et al. shows a handle 25 and proximal opening aligned with slide member 34, a channel 36, an entry slot 94 in connection with the channel 36 (Figure 2). In regard to claim 3, Lucey et al shows a housing around a portion of the slide member 34, which includes a cartridge that is removable from the handle and the lever (Figure 2). In regard to claim 4, the housing has a proximal opening included with suction means 38 aligned with slide member, a distally extending channel 36, and an entry slot 94 in communication with the channel. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to modify Lucey et al. with a slot in the slide member as taught by Shutt et al. since such modification would provide a receiving portion for the cam member.

6. Claims 5-6 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steadman et al. (5928252) in view Troutner et al (4091880). In regard to claim 5, Steadman et al. shows a modular surgical instrument 40, an actuator module comprising a handle 44 curved for gripping, an integral support portion shown (not numbered) in Figure 2A comprising the lower portion of housing 21, a lever 42 pivotally connected 43 to support portion of handle, the lever including a trigger portion (curvature indentations shown on lever 42 in Figure 2A) and drive portion (not numbered) includes the region on lever 42 above pivotal connection 43, a trigger portion

longer than the drive portion (Figure 2A), a tool module comprising a hollow housing 21, a hollow elongate support member 24, a passageway defined by the shaded region between the housing 21 and support member, a discrete surgical instrument 14 capable of motion in the proximal-distal direction (column 3 lines 5-10), and a discrete slide member 15. Steadman et al. lacks a discrete elongate support member and separate operation of the actuator and the tool modules. Troutner et al. teaches a surgical instrument 20, in which the discrete actuator 22 and discrete tool module 28 are held together by latch 30 (Figures 1 and 2). The actuator module may include a power pack for actuating the module providing the capability of the actuator and tool module being assembled and used independently of each other. Additionally, the tool module comprises an assembly of a hollow housing and a discrete elongate support member (Figure 2 consisting of the top region above reference numbers 52 and 54), a discrete surgical instrument 21 received in opening at 32 having a proximal part extending past the proximal end of hollow elongate support member into the housing, and a discrete slide member 74 having a drive surface within the housing, best illustrated in Figure 4c. In regard to claim 6, Steadman et al. shows a slide member 15 with an elongate slot 29 and the housing of the tool module 21 has an opening 23 aligned with the elongate slot 29. In regard to claim 11, Steadman et al. shows a cannula 41. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to modify Steadman et al. with a discrete elongate support member and a latch means to disassemble the actuator and tool module as taught by Troutner et al. since such modification would provide for the modules to be used independent of each other.

7. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Steadman et al. in view of Matthews et al. (6427351). Steadman et al. shows all of the claimed elements as set forth above including a slide member 15 in the housing 21. Steadman et al. lacks a pair of elongate distance references. Matthews et al. teaches a surgical instrument 10, comprising a handle 36, having a pair and flexible distance references 44 and 46 connected at proximal end 24 of slide member 30, 64 within housing 66 (Figure 2, column 2 lines 35-65). Therefore it would have been obvious for one having ordinary skill in the art at the time of the invention to modify Steadman et al. with a pair of elongate distance references as taught by Matthews et al. for the purpose of providing the surgical instrument with distance measurement means.

8. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Steadman et al. and Matthews et al. as applied to claim 7 above, and further in view of Burbank et al. (6331166). Steadman et al. shows the slide member 15 in housing 21. Matthews et al. teach a pair of flexible distance references 44 and 46 that are substantially straight and parallel in shape and divergent at the free ends, but lacks disclosure of the material composition of the references. Burbank et al. teaches a surgical instrument 10 comprising a cutting element 20 located at proximal end 14 of housing 18. The cutting element 20 is comprised of Nitinol a flexible memory metal (column 4, lines 55-65). Figure 1 illustrates 20 in an arcuate configuration demonstrating the flexibility of the Nitinol material. It would have been obvious for one having ordinary skill in the art at the time of the invention to modify Steadman et al. to include a pair of flexible distance references comprised of Nitinol as taught by Burbank

et al. since such modification would provide the distance references flexibility to adapt their shape configuration over a substantial range of distances.

9. Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steadman et al. in view of Shutt et al. (5507772). Steadman et al. shows all of the claimed elements as set forth above including a tool module housing 21 (Figure 2A) that is fitted with a cannula 128 removably connected by hub 129 (Figure 12, column 9, lines 7-10). Steadman lacks disclosure of other embodiments of the tool module. In regard to claims 12-14, Shutt et al. teaches a surgical instrument 10, comprising a kit including a actuator module 12 and tool module 140 wherein the tool module 140 can be replaced with additional tool modules (column 12, lines 42-54), and the handle 12 is sized and shaped to support the housing of the tool module 140 (Figure 12, column 12. lines 22-40). In regard to claim 15, Steadman shows the actuator module 44 and housing of tool module 21 that includes a spring 26 positioned with the slide member 15 to urge the slide member 15 toward the proximal end of housing 21 (column 3, lines 1-5). It would have been obvious to one having ordinary skill in the art at the time of the invention to modify Steadman et al. with a kit comprising an actuator and a plurality of tool modules and a handle sized appropriately as taught by Shutt et al. for the purpose of supporting the housing of the tool module.

10. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shutt et al. (5507772) in view of Matthews et al. (6427351) and Burbank et al. (6331166). Shutt et al. shows a disposable surgical tool module 140. Shutt et al. lacks a pair of elongate distance references made from a shape memory material. Matthews et al. teaches a

surgical instrument 10, comprising a handle 36, having a pair and flexible distance references 44 and 46, that are substantially straight and parallel in shape and divergent at the free ends, connected at proximal end 24 of slide member 30, 64 within housing 66 (Figure 2, column 2 lines 35-65). Burbank et al teaches a surgical instrument 10 comprising a cutting element 20 located at proximal end 14 of housing 18. The cutting element 20 is comprised of Nitinol a flexible memory metal (column 4, lines 55-65).

Figure 1 illustrates 20 in an arcuate configuration demonstrating the flexibility of the Nitinol material. It would have been obvious for one having ordinary skill in the art at the time of the invention to modify Shutt et al. to include a pair of flexible distance references comprised of Nitinol as taught by Matthews et al. and Burbank et al. since such modification would provide the distance references flexibility to adapt their shape configuration over a substantial range of distance measurements.

11. Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shutt et al. in view of Matthews et al. In regard to claim 22, Shutt et al. shows a surgical instrument 10 comprising a handle 20 including a grip portion 22 at proximal end; hollow elongate support member 142 extending outward from handle 20 in distal direction; a surgical implement 152; a lever 24 including a curved trigger portion (bottom 3 curves of Figure 12) pivotably connected to handle 20 via coupler 26, a drive portion (upper portion of 24 Figure 12) and the lever 24 extending through opening 111 in handle 20; slide member 154 having drive surface engaged with drive portion of lever (Figure 12-14). Shutt et al. lacks a pair of elongate distance references and a wedge with distance indicia. Matthews et al. teaches a surgical instrument 10, comprising a handle 36,

having a pair and flexible distance references 44 and 46, connected at proximal end 24 of slide member 30 via tubes 40 and 42 and extending out of distal end of cylindrical elongate support member 23 (Figure 1); wherein tubes 42 and 40 extend through discrete elongate tubes 22 and 23 having substantially straight and parallel in shape curved divergent portions at the free ends; wherein distance references 46 and 44 extend through the other end of discrete elongate tubes 22 and 23 having substantially straight and parallel in shape curved divergent portions at free ends. Matthews et al. does not expressly disclose that the ends of the distance references are beveled, however the apertures 26 and 28 have beveled openings and therefore the elongate distance references which emerge the from apertures may comprise the same beveled shape for ease of movement in and out of the apertures (Figure 1). At the time of the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to configure the distance references with beveled ends because Applicant has not disclosed that having beveled ends provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the distance references taught by Matthews et al. because both distance references perform the same function. In regard to claim 23, Matthews et al. shows curved portion of elongate tubes having a radius of curvature greater than 5 inches (Figure 13). In regard to claim 24, Matthews et al. shows a wedge 39 including distance indicia 72 between the discrete elongate tubes 22 and 23. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to modify Shutt et al.

with elongate distance references and a wedge including distance indicia as taught by Matthews et al. for the purpose of measuring distance.

***Response to Arguments***

12. Applicant's arguments filed May 19, 2006 have been fully considered but they are not persuasive.

13. Regarding claims 1-4, it is unclear what the Applicant is arguing. The Examiner believes that Lucey et al. in view of Shutt et al. shows the claimed invention. See rejection above.

14. Regarding claims 5-7 and 9, 11-15 the Applicant argues that there is not motivation to combine references. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it is obvious to one having ordinary skill in the art to make discrete components of a device useable together, in addition to providing the advantage of using the discrete components independent of the other. The Examiner, further notes that the invention claimed by the Applicant constitutes "discrete" elements, and in light of the broadest

reasonable definition of the term discrete the applied reference meet the limitations as claimed by Applicant. As broadly as structurally claimed, the Examiner believes that the applied art teaches the invention claimed by Applicant. See rejection above.

15. Regarding claims, 16-19 and 21, Applicant argues that Shutt et. al. does not disclose a housing and discrete hollow elongate support. The Examiner disagrees. Shutt et al. discloses that the housing 12 is configured to be removable coupled to the discrete elongate support 142 (column 8 lines 31-38 and column 12 lines 5-21). See rejection above.

16. Regarding claims 22-24, the Applicant argues that Shutt et al. nor Matthews et al. shows distance references with beveled ends. The Examiner disagrees. See rejection above.

### ***Conclusion***

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristin D. Rogers whose telephone number is 571.272.7293. The examiner can normally be reached on Monday through Friday 8:00am - 4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571.272.4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



MAX E. HINDENBURG  
SUPERVISORY PATENT EXAMINER  
TELEPHONE: (571) 272-4726

KDR